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1. Your reference

P13953 r4/r2/ro

20JUN01 E638479-1 D02656
P01/7700 0.00-0114939.2

2. Patent application number
(The Patent Office will fill in this part)

0114939.2

19 JUN 2001

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ANGIOMED GmbH & Co. MEDIZINTECHNIK KG

Wachhausstrasse 6
D-76227 KARLSRUHE
Germany

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

Germany

7395601002

4. Title of the invention

LUER CONNECTOR PORTION

5. Name of your agent *(if you have one)*

David Lethem

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Hoffmann Eitle
European Patent Attorneys
Sardinia House
52 Lincoln's Inn Fields
London WC2A 3LZ

Patents ADP number *(if you know it)*

07156466001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

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a) any applicant named in part 3 is not an inventor, or
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Patents Form 1/77

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Continuation sheets of this form	0
Description	8
Claim(s)	4
Abstract	0
Drawing(s)	2

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Priority documents	
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature

Date 19/06/01

12. Name and daytime telephone number of person to contact in the United Kingdom

David Lethem
Hoffmann Eitle 020 7404 0116

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DUPLICATE

Angiomed GmbH

19/06/01
Akte: 87143

Luer Connector Portion

This invention relates to a connector portion useful particularly, but not exclusively, as part of a device for passing fluid into an annular cavity between an inner elongate body and an outer elongate tubular body of a stent delivery system, and also relates to a stent delivery system making use of the same connector. In particular, this invention relates to a connector which comprises the male portion of a Luer connector. Furthermore, it relates to a device having a housing with a distal end, a proximal end and an off-axis end, wherein the housing provides a seating at the distal end thereof for an outer elongate tubular body along an axis of the housing extending between the proximal and the distal end, and wherein the distal and off-axis ends define respective openings which are in fluid communication with each other, and wherein the proximal end having a lumen enables the inner elongate body to extend from the housing both distally and proximally along the axis thereof. It relates as well to a stent delivery system using the above mentioned connector and device.

The deployment of stents at a stenting site within a human or animal body requires careful handling of the stent delivery system to be used for deploying the stent. Exact positioning of the stent at the site of the stenosis prior to and during deployment is essential. The accuracy with which the stent can be deployed with respect to the occlusion inside the body lumen, as well as the skills of the surgeon in controlling the stent delivery system, will have an impact on the outcome of the operation.

Normally, a guidewire is used, to advance a stent delivery system containing the stent to be deployed into the body to the site of the stenosis. Once the distal end of the delivery system has reached the stenting site and the stent to be released is correctly located, the stent is released. To deploy a self-expanding stent it is known to gradually withdraw an outer sleeve holding the stent in a radially compressed configuration and thereby allow the stent to radially expand and to anchor itself inside the body lumen. In commercially available delivery systems, the stent is prevented by an inner catheter from moving proximally with the sleeve as it retreats proximally, and is held in a radially compressed state by a co-axially disposed outer sleeve enclosing the stent and the inner catheter. The relative axial positions of the inner catheter and the outer sleeve are varied by manipulation of the delivery system.

Since the stent as well as the occlusion are not directly visible to the surgeon performing the operation, the stent deployment procedure requires a visualisation procedure, usually the injection of a radiopaque fluid, in order to visualise the location of the stent inside the body lumen. The fluid is injected into an annular cavity between the inner catheter and the outer sheath. The position of the stent as well as the location of the stenosis itself can then be monitored from outside the patient's body by using X-ray imaging machines showing the images of radiopaque marker rings on the distal end of the delivery system and a reduced intensity image corresponding to the constricted volume of radiopaque fluid through the occluded site. This allows the surgeon/radiologist to find the location of the stenosis and place the stent with sufficient accuracy.

During the course of the delivery procedure, the radially compressed stent is held axially at a fixed position by a pusher surface of the inner catheter, which typically abuts the proximal end of the stent inside the outer sheath of the

delivery system. The proximal movement of the outer sheath to release the stent exerts a proximally directed force onto the stent which urges the stent to move in the same way. The surgeon has to counteract this tendency of the stent to move proximally by applying an adequate distally directed force onto the pusher element in order to off-set the opposing forces and to thereby keep the position of the stent fixed.

Typically, the stent is mounted into the delivery system at a manufacturing site. Then, the entire assembly is sterilised and air-tightly packed in a specially designed sealed enclosure. During sterilisation and packaging, there is always the risk that the co-axial components of the assembly might move so that the outer sheath may be displaced with respect to the inner catheter. Consequently, the position of the stent might be changed during these steps prior to its placement.

Therefore, it would be desirable to have a delivery system with a fluid injection port which is protected against inadvertent or premature movement of the outer sheath relative to the stent but is still simple to use and economical to manufacture.

Summary of the Invention

It is therefore an object of the invention to provide a stent delivery system which is inexpensive to manufacture and easy to use and enables the surgeon to lock the position of the inner catheter with respect to the outer sleeve and to inject fluid into the annular cavity between the inner catheter and the outer sleeve in known manner.

This object has been achieved by a simplified delivery system using the same component for locking the position of the inner catheter with respect to the outer sleeve and for

injecting radiopaque fluid into the cavity between the inner catheter and the outer sleeve.

A stent delivery system which achieves the above-mentioned object is described in independent claim 16. The locking mechanism is provided by means of a locking end release device which is defined in independent claim 9. The pressure pad being part of the locking and release device is defined in independent claim 1.

Further preferred embodiments of the present invention are described in dependent claims.

Brief Description of the Drawings

The accompanying figures, referred to herein and constituting a part hereof, illustrate preferred embodiments of the present invention, and together with the description serve to explain the principles of the invention.

Figure 1 shows a cross-sectional view of a device having the locking and release device attached thereto;

Figure 2 shows a perspective view of a stent delivering system using the locking and release device of the invention.

Figure 1 shows a cross-sectional view of a device for passing fluid into an annular cavity 30 between an inner catheter 26 and an outer sleeve 28.

The device has the shape of a T-piece 2 comprising a distal end 24, a proximal end 12 and an off-axis end 36. It is the distal 24 and the proximal 12 end which define the axis of the device. The outer sleeve 28 is attached to the threaded distal end 24 of the device via a threaded female collar 22. The female collar 22 comprises a central through-hole through

which the outer sleeve 28 is inserted and thermally clamped to the female collar 22. Thermally clamping means that the material used for the outer sleeve 28 expands upon thermal heat treatment and retains its expanded shape when it returns back to ambient temperature. Hence, the outer sleeve 28 remains attached to the collar 22 when the process of thermal treatment is completed. It is also conceivable to use other means to attach the outer sleeve 28 to the distal end of the device, such as a press-fitting using re-entrant surfaces or suitable adhesives. A seating 25 of the housing seals with a complementary seating 27 of the threaded collar 22.

The proximal end 12 of the device, as shown in Figure 1, exhibits a recess having two different diameters whereby the innermost recess 14 in an axial direction accommodates an O-ring 18 for providing a fluid-tight seal with the inner body and a plug 20 press-fitted into the larger diameter recess 16 in order to prevent the O-ring from slipping out of the smaller recess upon proximal movement of the inner body. It is also conceivable to screw the plug into the larger diameter recess or use an appropriate adhesive. Differently sized O-rings can be used to accommodate differently sized inner catheters for differently sized stents. This further enhances the versatility of the device.

The off-axis end 36 of the device shows a female Luer-lock assembly 34 which connects to a male Luer-lock assembly 32 of the locking and release device 1. The locking and release device 1 may also be referred to as a Luer-lock connector and comprises a passage 38 therethrough for passing fluid down the inner bore of the Luer connector. The end of the Luer connector 1 facing the off-axis end of the T-piece comprises a spigot 6 which is inserted into the internal bore 38 of the Luer connector. In this preferred embodiment the spigot is fixed inside the bore 38 of the Luer connector by means of an annular cutting edge which cuts itself into the material of the Luer connector and thereby fixedly fastens the spigot 6

to the Luer connector 1. It is also conceivable to screw or press-fit the spigot into the Luer connector. The spigot 6 comprises a cut-out portion 40 at the end extending into the T-piece for providing a continuous passage for the fluid to be injected. The lower (in Fig. 1) end of the spigot comprises re-entrant surfaces onto which an elastically deformable elongate locking member 8 is attached. The locking member 8 is preferably made out of silicone rubber but other soft materials, such as Viton, can be used. The end surface of the locking member 8, remote from the spigot 6, constitutes a pressure pad which bears on the inner catheter 26 when the locking member is in its locking disposition, as explained below.

A distinct feature of the Luer connector is its quick and easy installation, since it requires only less than half a turn to fully engage the Luer-lock connector with the female portion of the mating Luer-lock on the off-axis of the T-piece. The dimensions of the spigot and the pressure pad are such that when bringing the Luer-lock connector into full engagement with the device, the deformable locking member 8 extends sufficiently far enough beyond the end of the Luer-lock connector so that it experiences a compressive force due to pressing down onto the inner catheter 26. This means that, in the absence of the inner catheter, the elastic member intersects the locus or line of presence of the inner body, so that it undergoes deformation when the inner body in present. It is this compression of the locking member which prevents axial sliding movement of the inner body within the device. In this locking disposition, fluid can still be injected through the Luer-lock connector down into the annular cavity between the inner body and the outer sleeve. For ease of use, a syringe can easily be attached to the upper end 39 opposite the one being connected to the T-piece of the Luer connector via a Luer-lock connection, which upper end 39 for this purpose can exhibit the characteristic cone angle of a female Luer-lock portion.

The Luer connector optionally comprises a safety catch which prevents inadvertent release of the Luer connector from the T-piece. The safety catch illustrated comprises two components, a pawl 34 located on the Luer connector and preferably glued thereon and a breakable catch 35 which prevents rotation of the Luer connector when the pawl 34 and the catch are engaged. To release the safety catch, the Luer connector is rotated counter-clockwise thereby breaking the pawl to disengage the pawl from the catch. The pawl and the catch are preferably made of polymeric material. It is also conceivable to bring the pawl 34 into engagement with a spring-biased toothed annulus 35 on the housing 2 close to the off-axis end of the T-piece. To disengage the safety catch, the spring-biased toothed annulus 35 is pushed towards the T-piece, thereby releasing the pawl and disengaging the Luer connector. Also, a pin for blocking the rotation of the Luer connector or any other conventional locking mechanism being suitable in size and weight can be used.

The entire structure is preferably made out of synthetic polymeric materials in order not to add any additional weight to the stent delivery system which would impair the handling of the system.

Figure 2 shows a perspective view of a stent delivery system using the locking and release device as well as the T-piece of Figure 1 in an assembled state. The delivery system is based on a trigger-principle for the proximal withdrawal of the outer sleeve with respect to the inner catheter. The proximal and distal end of the T-piece connector are engaged with mating parts of the delivery system, whereby the proximal end 50 of the inner catheter is fixed in position by a mount 52 at the rear side of the trigger device. Upon actuation of the delivery system the T-piece is drawn rearwardly with every squeeze of the trigger 54 towards the

rear end 52 of the hand-held device and thereby withdraws the outer sheath 28 to gradually release the stent.

During insertion of the stent into the delivery system, sterilisation and transport, the Luer-lock connector remains in its locking disposition, thereby preventing inadvertent sliding movement of the inner catheter with respect to the outer sleeve. It is only shortly before deploying the stent into the body lumen, that the Luer-lock connector 1 is disengaged from the T-piece 2. Once the stent has been properly placed at the site of the stenosis, the surgeon uses the trigger mechanism in order to proximally withdraw the outer sleeve and to release the stent. In case the surgeon has to temporarily interrupt the procedure of stent placement, the Luer-lock connector can be inserted back into the T-piece in order to fix the position of the inner catheter with respect to the outer sleeve.

Although the illustrated embodiment shows a single T-piece being used for both introduction of radiopaque marker fluid and for clamping the inner catheter relative to the outer sheath, and although this is a useful advantage of the invention, nevertheless it will be appreciated that separate T-pieces could be used for these two separate functions. The advantage delivered by this invention, namely reliable and economical inner catheter clamping remains, even if radiopaque fluid is delivered elsewhere.

C L A I M S

1. A connector which comprises the male portion of a Luer connector,
characterised in that
the male portion is extended axially into a pressure pad having a pressure surface.

2. Connector according to claim 1, characterised in that the pressure pad is elastically deformable.

3. Connector according to claims 1 or 2, characterised in that the pressure pad is made of silicone rubber.

4. Connector according to any one of the preceding claims, characterised in that the locking member is elongate and mounted co-axially at one of its ends to the connector, the other end providing the pressure surface.

5. Connector according to claim 4, characterised in that said one end of the pressure pad is attached to a spigot which is itself joined to the male portion, the spigot being shaped to permit passage of fluid through the connector.

6. Connector according to claim 5, characterised in that the spigot is engaged with the male portion of the connector by an annular cutting edge.

7 Connector according to claim 5 or 6, characterised in that the spigot comprises a re-entrant surface by which the spigot and pressure pad are attached to each other.

8. Connector according to any one of the preceding claims, characterised in that the connector further comprises a female portion of a Luer connector.

9. A device for passing fluid into an annular cavity between an inner elongate body and an outer elongate tubular body, the device having a housing with a distal end, a proximal end and an off-axis end, the housing providing a seating at the distal end thereof for the outer elongate tubular body along an axis of the housing extending between the proximal and the distal end, the distal and off-axis ends defining respective openings which are in fluid communication with each other, and the proximal end having a lumen to enable the inner elongate body to extend from the housing both distally and proximally, along the axis thereof:
characterised by:

a pressure pad mounted to the housing and extending into the cavity from the off-axis opening of the housing and movable between a locking disposition, in which the pad bears on the locus of the inner elongate body for preventing axial movement thereof with respect to the outer body, and simultaneously allows injection of fluid into the annular cavity, and a release disposition in which the pad is spaced from the locus of the inner elongate body for permitting axial movement of the inner body with respect to the outer body.

10. Device according to claim 9, wherein the pressure pad is carried on the male portion of a Luer connector, and wherein the male portion of the Luer connector connects to a mating female portion on the off-axis end of the housing.

11. Device according to claim 9 or 10, characterised in that the pressure pad is moved between the locking and release disposition by a rotation of substantially less than half a turn.

12. Device according to any one of claims 9 to 11, characterised by an O-ring inside a recess at the proximal end of the housing to provide a fluid-tight seal with the inner body.

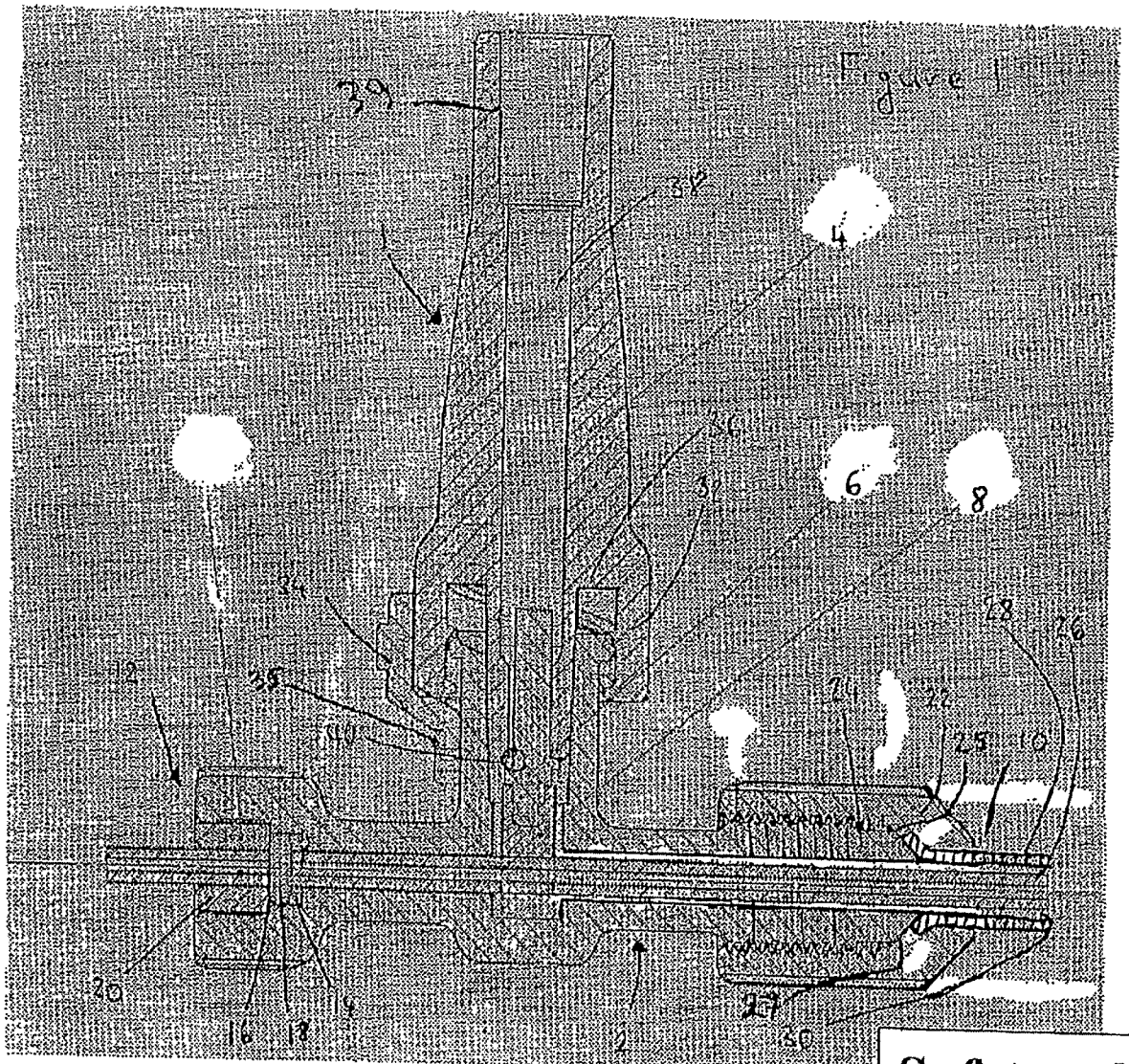
13. Device according to claim 12, characterised by a plug at the proximal end of the housing to return the O-ring in the recess during proximal movement of the inner body.

14. Device or connector according to any one of the preceding claims, characterised by a safety catch to prevent premature or inadvertent release of the inner elongate body from the pressure pad.

15. Device or connector as claimed in claim 14 wherein the safety catch comprises a breakable pawl engageable with a toothed annulus on the housing.

16. Stent delivery system comprising an inner elongate body and an outer elongate tubular body which are co-axially arranged, a pull-back device enabling proximal displacement of the outer body with respect to the inner body for releasing a stent contained within an annular cavity formed between the inner and outer body, into a body lumen, a device for passing fluid into the annular cavity having a housing with a distal end, a proximal end and an off-axis end, the housing provides a seating at the distal end thereof for the outer elongate tubular body along an axis of the housing extending between the proximal and the distal end, the distal and off-axis ends defining respective openings which are in fluid communication with each other, and the proximal end having a lumen to enable the inner elongate body to extend from the housing both distally and proximally, along the axis thereof, the stent delivery system being characterised by

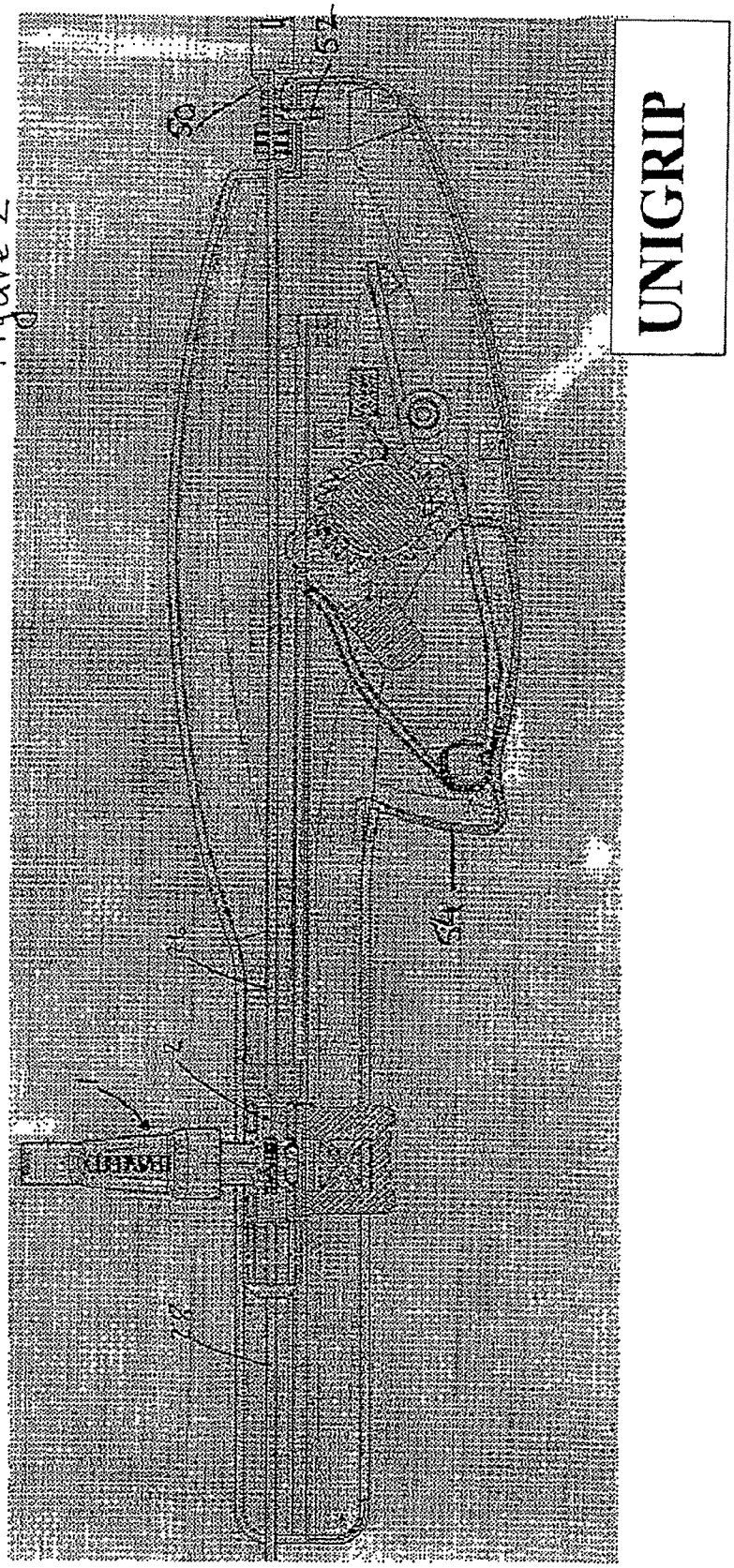
a locking and release device mounted to the housing and extending into the off-axis opening of the housing to bear, in a locking disposition, against the inner body to prevent axial movement thereof with respect to the outer body, and to simultaneously allow injection of fluid into the annular cavity and, in a released disposition, to be spaced from the inner body to permit axial movement of the inner body with respect to the outer body.



Safety adapter

1/2

Figure 2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